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10/686,072	10/15/2003	Anselmo Najera G.		7975

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,072

Applicant(s)

G. ET AL.

Examiner

Kathleen Sonnett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/15/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/15/2003.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 2, 7, 8, 9, 16 and 17 use the term "vertical delineator" and there is no antecedent basis for this term in the specification. The examiner is assuming that the term "vertical delineator" was erroneously used in place of "vaginal delineator" and is treating the term "vertical delineator" in claims 2, 7, 8, 9, 16, and 17 to mean "vaginal delineator".

Claim Objections

2. **Claim 12** is objected to because of the following informalities: minor typographical error. It appears to the examiner that the phrase "wherein the shaft" should be removed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 3, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Nicholas (U.S. 5,431,662). Nicholas discloses a uterine manipulating device comprising a curved shaft (214) with a radius of curvature of 8 inches, a handle end (212) of slightly larger diameter than the shaft, a uterine tip end (221) of slightly smaller diameter than the shaft, a vaginal delineator (240), and a means for attaching the vaginal delineator to the shaft (274) (Fig. 13, 18, and col. 8 lines 43-62, col. 10 lines 1-21). Uterine tip end (221) is a crowned atraumatic tip and as seen in Fig. 18, as you near the distal end of the uterine tip, the diameter becomes smaller than the diameter of the shaft.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-3, 7-9, 12, and 16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. (U.S. 5,643,285) in view of Nicholas (U.S. 5,431,662). Rowden et al. discloses a uterine manipulating device comprising a shaft (16), having a handle end (28) of a slightly larger diameter than the shaft, a uterine tip (64) of slightly smaller diameter than the shaft, a vaginal delineator (20) and means for attaching the

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vaginal delineator to the shaft (col. 4 lines 47-59). Rowden et al. fails to disclose that the shaft has a curved shape of a female cervix.

5. However, Nicholas discloses that it is old and well known in the art to shape uterine manipulating devices in a general curved shape of a female cervix. Nicholas further discloses a radius of curvature of the shaft to be 8 inches (col. 8 lines 43-61). This shape facilitates insertion of the device into a patient. Nicholas also discloses that it is old and well known in the art to include a handle and shaft that are threaded so as to be removably attached to each other ([0093]). A manipulator with a removable handle gives the advantage of being easy to sterilize. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Rowden et al. to include a curved shaft and handle and shaft that are removably attached as made obvious by Nicholas in order to gain the advantage of easy insertion and easy sterilization of the device.

6. Regarding claims 7, 8, 16, and 17, Rowden et al. discloses an outer diameter for the vaginal delineator as 1.436 inches (col. 5 lines 1-6). Therefore, a diameter of 1.5 with regards to claims 7 and 16, and a diameter of 1.6 inches with regards to claims 8 and 17 is considered obvious since no criticality is given in the specification of the instant patent application for a diameter of 1.436 inches. Also, it is the examiner's position that a device that is 0.164 inches smaller than 1.6 inches will perform as well as a delineator with a diameter of 1.6 inches.

7. **Claims 10 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. and Nicholas et al. as applied to claim 1 above and in further view of

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Harris (U.S. 4,430,076). The modified device of Rowden et al. discloses the invention substantially as stated above but fails to disclose a diameter of 2.54 cm for the handle.

However, Harris discloses that it is old and well known in the art to size a handle for a uterine manipulating device to be *about* 2 cm. There is no criticality given in the specification for a diameter of between 2.03 and 3.8 cm or a diameter of 2.54 cm for the handle. It is the examiner's position that a device with a handle having a diameter that is 0.54 cm less than the claimed 2.54 cm value will perform equally as well. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Rowden et al. to include a handle which measures 2.54 cm because Harris discloses that *about* 2 cm is an effective diameter for a handle on a uterine manipulating device.

8. **Claims 4 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. in view of Nicholas as applied to claim 1 above and in further view of Fox et al. (U.S. 5,437,628). The modified device of Rowden et al. discloses the invention substantially as stated above but fails to disclose that the radius of curvature is 6 inches.

9. However, Fox et al. discloses that it is old and well known to give a radius of curvature of 6 inches to a device that will be inserted into the vaginal canal in order to facilitate an easy insertion (col. 3 lines 27-40). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Rowden et al. to include a shaft with a radius of curvature of 6 inches made obvious by Fox et al. in order to follow the path of the vaginal canal and cervix for easy insertion.

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10. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. in view of Nicholas et al. as applied to claim 1 above and in further view of Hasson (U.S. 5,562,680). The modified device of Rowden et al. discloses the invention substantially as stated above, but fails to disclose that the uterine tip and the end of the shaft opposite to the handle are threaded so as to be removably attached to each other.

11. However, Hasson discloses that it is old and well known in the art to include a uterine tip and shaft that are threaded so as to be removably attached to each other (Fig. 8, col. 4 lines 30-33). This allows for the interchange of different uterine tips. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Rowden et al. to include a uterine tip and shaft that are threaded so as to be removably attached to each other as made obvious by Hasson in order to be able to interchange uterine tips and for ease of cleaning.

12. **Claims 5, 6, 14, and 15** rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. and Nicholas as applied to claim 1 above, and further in view of Singh et al. (U.S. 6,423,075) and Smith et al. (U.S. 5,645,561). The modified device of Rowden et al. discloses the invention substantially as stated above, but fails to disclose values for the diameter of the shaft, the diameter of the uterine tip end, or the length defined by the distance between the end of the uterine tip and the vaginal delineator.

13. However, Smith et al. discloses a uterine manipulator with a uterine tip (54) that has a diameter of *about* 0.2 inches (col. 8 lines 4-7 and Fig. 2). Smith et al. further discloses that the distance between the uterine tip and the vaginal delineator is from about 6 cm to about 8 cm. Although the diameter of *about* 0.2 inches for the uterine tip

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does not fall within the broad range of 0.25 to 0.45 inches and further does not match the value given in claim 6 and 15 of 0.375 inches, it is the examiner's position that a device with a uterine tip having a diameter of about 0.2 inches will perform equally as well as a device with a uterine tip having a diameter of 0.375 inches. Additionally, no criticality is given in the specification for the specific diameter value. Regarding the diameter of the shaft, Singh et al. discloses that it is old and well known in the art to include on a uterine manipulating device a shaft with a diameter between 10 mm and 30 mm. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Rowden et al. to include the dimensions made obvious by Smith et al. and Singh et al. because the dimensions are given as effective dimensions for uterine manipulating devices and no criticality is given in the specification for the particular values of the claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 2001/0021854 to Donnez et al.

U.S. 5,464,409 to Mohajer.

U.S. 5,549,563 to Kronner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCS


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

4/15/06.